

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Reinhard BOLLI <i>et al.</i>)	Group Art Unit: 1644
)	
Serial No.: 10/579,357)	Examiner: Kim YUNSOO
)	
Filed: May 16, 2006)	
)	Confirmation No.: 2138
For: IMMUNOGLOBULIN)	
PREPARATIONS HAVING)	
INCREASED STABILITY)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action mailed May 12, 2008, Applicant respectfully requests reconsideration of this application in view of the election and remarks below.

This response is due by June 12, 2008, and is timely filed.

According to the Examiner, pending claims 1-23 are not so linked as to form a single general inventive concept under PCT Rule 13.1, and the Examiner required restriction under 35 U.S.C. § 121 and 372 between:

- | | |
|----------|---|
| Group I | Claims 1-17 and 23, drawn to a stable protein preparation comprises one or more stabilizers; |
| Group II | Claims 18-22, drawn to a method of stabilizing protein preparation comprising an aqueous protein solution and adding one or more stabilizers. |

Solely to facilitate prosecution and without prejudice or disclaimer, Applicant provisionally elects to prosecute Group I, claims 1-17 and 23, drawn to stable protein preparations comprises one or more stabilizers. Applicant makes this election with traverse for the reasons set forth below.

The Examiner stated that the inventions as listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features. The Examiner alleged that the inventions of Groups I-II were found to have no special technical feature that defined the contribution over the prior art of WO 98/28007 ('007). Office Action at 2. Specifically, the Examiner purported that the '007 publication teaches a liquid composition comprising an interferon and arginine or glycine at pH 5.0 and a process for stabilizing interferon-beta in liquid pharmaceutical composition with stabilizers, and therefore the '007 anticipates the claimed pharmaceutical composition and a method of stabilizing of claims. *Id.* Applicants respectfully disagree.

Contrary to the Office's assertions, Applicants respectfully submit that the claimed inventions share a special technical feature. That is, each of the claims require a preparation comprising one or more stabilizers selected from the group consisting of non-polar and basic amino acids and wherein the preparation has a pH of 4.2 to 5.4. Such a preparation represents a contribution made by the invention as a whole over the prior art. Accordingly, all of the claims form a single general inventive concept and satisfy the requirements for Unity of Invention under PCT Rule 13.1. MPEP, Appendix AI (Administrative Instructions under the PCT), Annex B, Part 1, subsection (b); Rule 13.2.

Additionally, and as the Examiner kindly pointed out, election of the composition claims allows for rejoinder of method claims from Group II upon the allowance of the composition claims, provided that the method claims are amended to have the same scope as the composition claims. Applicants intend to rejoin the claims from Group II at the appropriate time.

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application, withdrawal of the restriction requirement, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 12, 2008

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